

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of  
Fedde, et al.

Serial No. 10/682,527

Filed: October 9, 2003



Attorney Docket No. 3417/03

Group Art Unit: Unknown

Examiner: Unknown

For METHODS FOR THE TREATMENT OR PROPHYLAXIS OF ALDOSTERONE-MEDIATED PATHOGENIC EFFECTS IN A SUBJECT USING AN EPOXY-STERIODAL ALDOSTERONE ANTAGONIST

January 16, 2004

Commissioner of Patents  
PO Box 1450  
Alexandria, VA 22313

SIR:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit herewith various documents cited on the attached Form PTO 1449. Applicants respectfully request that the Examiner consider and enter all the documents cited on the enclosed Form PTO 1449 into the file of the above-identified application. Applicants also request an indication of the same by return of the Form PTO 1449 being initialed and dated by the Examiner.

Please charge the fee of \$180.00 as required by 37 C.F.R. § 1.17(p) to Deposit Account No. 19-1025. No additional fees are believed due to ensure consideration of the attached documents by the Examiner. However, if any additional fees are required or an overpayment of fees made, the Commissioner is hereby authorized to debit or credit our Deposit Account No. 19-1025, as necessary.

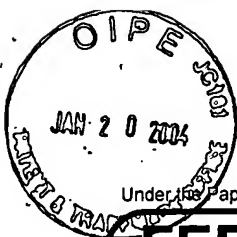
Respectfully submitted,

Joseph R. Schuh, Reg. No. 48,180  
Agent for Applicants  
(314) 274-8182 (St. Louis)

Pharmacia Corporation  
Corporate Patent Department  
P.O. Box 1027  
Chesterfield, MO 63006

01/22/2004 AWONDAF1 00000040 191025 10682527

01 FC:1806 180.00 DA



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) \$180.00

## Complete if Known

Application Number	10/682,527
Filing Date	October 9, 2003
First Named Inventor	Fedde et al
Examiner Name	Unknown
Group Art Unit	Unknown
Attorney Docket No.	S0-3417/3

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit  
Account  
Number

19-1025

Deposit  
Account  
Name

Pharmacia Corporation

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1)					(\$)

### 2. EXTRA CLAIM FEES FOR UTILITY AND

Total Claims		Extra Claims		Fee from below		Fee Paid
		-20** =	0	X		0.00
Independent Claims		-3** =	0	X		0.00
Multiple Dependent						

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	18	2202	9	Claims in excess of 20	
1201	84	2201	42	Independent claims in excess of 3	
1203	280	2203	140	Multiple dependent claim, if not paid	
1204	84	2204	42	** Reissue independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$) \$0.00

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non - English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR § 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Statement	180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
Other fee (specify)					

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) \$180.00

## SUBMITTED BY

Name (Print/Type) Joseph R. Schuh  
Signature *Joseph R. Schuh*

Registration No.  
(Attorney/Agent)

48,180

## Complete (if applicable)

Telephone

314-274-8182

Date

1/16/04

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



<b>FORM PTO-1449</b> U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)	<b>ATTY. DOCKET NO.:</b> S03417/03	<b>APPLICATION NO.:</b> 10/682,527
	<b>INVENTOR:</b> Fedde, et al.	
	<b>Filed:</b> 10/9/03	<b>Group:</b>

**U.S. PATENT DOCUMENTS**

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	1	4559332	12/17/1985	Grob et al.	514	175	09 APR 1984
	2	5145684	09/08/1992	Liversidge et al.	424	489	25 JAN 1991
	3	5318767	06/07/1994	Liversidge et al.	424	4	10 AUG 1992
	4	5384124	01/24/1995	Courteille et al.	424	430	12 FEB 1992
	5	5747001	05/05/1998	Wiedmann et al.	424	45	24 FEB 1995

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	6	WO9721720	✓ 19.06.97	US	C07J	21/00	X	
	7	WO9825948	✓ 18.06.98	US	C07J		X	
	8	WO9640257	✓ 19.12.96	US	A61K	45/06	X	
	9	EP0122232	✓ 10.04.84	Europe	C07J	71/00		X
	10	WO0027380	✓ 18.05.00	US	A61K	31/00	X	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

Examiner Initial		
	11 ✓	Funder, John W., <i>Current Opinion in Endocrinology and Diabetes</i> , 7(3): 138-142, 2000
	12 ✓	Epstein, M., et al., <i>Journal of the American Society of Nephrology</i> , Vol. 9, 322A-323A, September 1998
	13 ✓	Luft, FC, <i>Wiener Klinische Wochenschrift</i> , 110/13-14: 459-566, 31 July 1998
	14 ✓	Rabasseda, X., et al., <i>Drugs of the Future</i> , Volume 24, (5) : 488-501, 1999
	15 ✓	Ichikawa, S., et al., <i>Japanese Circulation Journal</i> , 48(11): 1184-1196, 1984
	16 ✓	Blumenfield and Laragh, <i>Congestive Heart Failure Pathophysiology, Diagnosis &amp; Management</i> , 1 <sup>st</sup> edition, Caddo (OK), Professional Communications, Inc., 1994
	17 ✓	MacMahon, S., et al., <i>Lancet</i> , 335:765-774, 1990
	18 ✓	United States Renal Data System 1999 Annual Data Report, <i>American Journal of Kidney Disease</i> , 34, Suppl 1: S1-S176, 1999
	19	Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, <i>Arch Internal Medicine</i> , 157: 2413-2446, 1997
	20	Dzau, VJ, et al., <i>Circulation</i> , 63:645-651, 1981
	21	Gerber, JG, et al., "Antihypertensive Agents & Drug Therapy of Hypertension" from <i>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</i> , 8 <sup>th</sup> edition, New York: McGraw-Hill, pp 784-813, 1993
	22	Weber, KT, et al., <i>Circulation</i> , 75(Suppl I): I40-I47, 1987
	23	Struthers, AD, <i>Journal of Cardiac Failure</i> , 2(1): 47-54, 1996
	24	Rocha, R., et al., <i>American Journal of Hypertension</i> , 12: 76A, 1999
	25	Staessen, J., et al., <i>Journal of Endocrinology</i> , 91: 457-465, 1981
	26	Pitt, B., <i>Cardiovascular Drugs and Therapy</i> , 9: 145-149, 1995
	27	Marayev, V., et al., <i>Presentation at the International Meeting on Heart Failure, 1995, Amsterdam, The Netherlands</i>

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	




<b>FORM PTO-1449</b> U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)	<b>ATTY. DOCKET NO.:</b> S03417/3	<b>APPLICATION NO.:</b> 10/682,527
	<b>INVENTOR:</b> Fedde, et al.	
	<b>Filed:</b> 10/9/03	<b>Group:</b>

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

Examiner Initial		
	28	Greene, E., et al., <i>Journal of Clinical Investigation</i> , 98: 1063-1068, 1996
	29	Hené, RJ, et al., <i>Kidney International</i> , 21: 98-101, 1982
	30	Berl, T., et al., <i>Kidney International</i> , 14: 228-235, 1978
	31	Ibrahim, HN, et al., <i>Seminars in Nephrology</i> , 17: 431-440, 1997
	32	Quan, ZY, et al., <i>Kidney International</i> , 41: 326-333, 1992
	33	Gavras, H., et al., <i>Circulation Research</i> , 36: 300-309, 1975
	34	Horiuchi, M., et al., <i>American Journal of Physiology</i> , 264 (2 Part 2) F: 286-291, 1993
	35	Ullian, ME, et al., <i>American Journal of Physiology</i> , 272 (3 Part 2) H: 1454-1461, 1997
	36	Hansson, L., et al., <i>Lancet</i> , 351: 1755-1762, 1988
	37	Joint National Committee, The 6 <sup>th</sup> Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, <i>NIH Publication Number 98-4080</i> , November 1997
	38	Kaplan, NM, <i>Journal of Hypertension</i> , 13 (Suppl 2): S113-S117, 1995
	39	Swedberg, K., et al., <i>Circulation</i> , 82: 1730-1736, 1990
	40	AIRE Study Group, <i>Lancet</i> , 342: 821-828, 1993
	41	Pitt, B., et al., <i>The New England Journal of Medicine</i> , 341 (10): 709-717, 1999
	42	The RALES Investigators, <i>American Journal of Cardiology</i> , 78: 902-912, 1996
	43	Kannel, WB, et al., <i>American Heart Journal</i> , 108: 1347-1352, 1984
	44	Maki, DD, et al., <i>Arch Internal Medicine</i> , 155: 1073-1082, 1995
	45	Heeg, JE, et al., <i>Kidney International</i> , 36: 272-280, 1989
	46	MacGregor, GA, et al., <i>Experiments in Hypertension</i> , 5: 1367-1380, 1983
	47	Buter, H., et al., <i>Nephrology Dial Transplant</i> , 13: 1682-1685, 1998
	48	Weir, J., <i>Journal of Human Hypertension</i> , 11: 17-21, 1997
	49	Pratt, JH, et al., <i>Hypertension</i> , 34: 315-319m 1999
	50	<i>The Merck Manual</i> , 17 <sup>th</sup> edition, pp 1526-2528, 1999
	51	Ganong, WF, <i>Review of Medical Physiology</i> , 6 <sup>th</sup> edition, Lange Medical Publications, Los Altos, Calif.
	52	American Heart Association Nutrition Committee, "Dietary Guidelines for Healthy American Adults," <i>Circulation</i> , 77: 721-724, 1988
	53	NIH News Release: "NHLBI Study Shows Large Blood Pressure Benefit From Reduced Dietary Sodium," May 17, 2000
	54	Bakris, GL, et al., <i>American Journal of Hypertension</i> , 9: 200S-206S, 1996
	55	Campese, VM, <i>Hypertension</i> , 19: 403-418, 1992
	56	Neaton, JD, et al., <i>JAMA</i> , 270: 713-724, 1993
	57	Grim, CE, et al., <i>Journal of Chronic Disease</i> , 33: 87-94, 1980
	58	Van Brummelen, P., et al., <i>Acta Med Scand.</i> , 204: 151-157, 1978
	59	Weinberger, MH, et al., <i>JAMA</i> , Volume 259 (17): 2561-2565, 1988
	60	Sullivan, JM, <i>Hypertension</i> , 17 (Suppl I): I61-I68, 1991
	61	Weir, MR, et al., <i>Hypertension</i> , 16: 235-244, 1990

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

	<b>FORM PTO-1449</b> U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE	<b>ATTY. DOCKET</b> NO.: S03417/3	<b>APPLICATION NO.:</b> 10/682,527
	<b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>	<b>INVENTOR:</b> Fedde, et al.	
	(Use several sheets if necessary)	<b>Filed:</b> 10/9/03	<b>Group:</b>

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

Examiner Initial		
	62	Brenner, K., <i>Current Opinions in Nephrology Hypertension</i> , 2(3): 341-349, May 1993
	63	Grim, et al., <i>Hypertension</i> , 1 476-485, 1979
	64	Strazzullo, et al., <i>Journal of Nephrology</i> , 13: 46-53, 2000
	65	Powers, DR, et al., <i>Archives of Internal Medicine</i> , 158: 793-800, 1998
	66	Ruthledge et al., <i>Journal of Hypertension</i> , 13: 953-955, 1995
	67	Svetkey, et al., <i>Hypertension</i> , 29: 918-922, 1997
	68	Cusi, D., et al., <i>Lancet</i> , 349: 1353-1357, 1997
	69	Lovati, E., et al., <i>Journal of Clinical Endocrinology and Metabolism</i> , 84: 3745-3749, 1999
	70	Ferrari, P., et al., <i>Kidney International</i> , 57: 1374-1381, 2000
	71	Giner, et al., <i>Hypertension</i> , 35: 512-517, 2000
	72	Yanagiagwa, M., et al., <i>Nature</i> , 332: 411-415, 1988
	73	De Nucci, G., et al., <i>Proceedings of the National Academy of Science, USA</i> , 85: 9797-9800, 1988
	74	Schiffirin, EL, et al., <i>American Journal of Hypertension</i> , 4: 303-308, 1991
	75	Elijovich, F., et al., <i>Hypertension</i> , 33: 1075, 1999
	76	Saruta, T., <i>Journal of Clinical Therapeutic Medicine</i> , 13: 4024-4029, 1997
	77	Shimamoto, K., <i>Japanese Cases, Nihon Rinsijo (Clinical Medicine in Japan)</i> , 58: 593-596, 2000
	78	Nakagawa, H., et al., <i>Human Hypertension</i> , 13 (11): 735-741, November 1999
	79	Kobayashi, Y., et al., <i>Japanese Circulation Journal</i> , 47 (2): 268-275, 1983
	80	Guidelines on Treatment of Hypertension in Elderly, 1995, <i>Comprehensive Research Projects on Aging and Health, the Ministry of Health and Welfare of Japan</i>
	81	Ogihara, T., et al., <i>Nippon Ronen Igakkai Zasshi</i> , 33 (12): 945-975, 1996
	82	Mizushima, S., <i>Clinical Experiments in Pharmacology and Physiology</i> , 26: 573, 1999
	83	Svetkey, LP, et al., <i>Hypertension</i> , 28: 854-885, 1996
	84	Eisner, GM, <i>American Journal of Kidney Disease</i> , 16 (4 Suppl 1): 35-40, 1990
	85	Flack, JM, et al., <i>Journal of Association of the Academy of Minority Physicians</i> , 2: 143-150, 1991
	86	Flack, JM, et al., <i>Hypertension</i> , 17 (1 Suppl): 1115-1121, 1991
	87	Ferri, et al., <i>Diabetes</i> , 48: 1623-1630, 1999
	88	Di Genaro, C., et al., <i>Hypertension</i> , 35: 869-874, 2000
	89	Bonner, <i>MMW Fortscher Medicine</i> , 14: 34-36, 1999
	90	Dimsdale, et al., <i>American Journal of Hypertension</i> , 3: 429-435, 1990
	91	Falkner, B., et al., <i>American Journal of Clinical Nutrition</i> , 65: 618S-621S, 1997
	92	Rocchini, AP, et al., <i>American Journal of Medical Science</i> , 307 (Suppl 1): S75-S80, 1994
	93	Weinberger, MH, Presentation at the 54 <sup>th</sup> Annual Conference of the American Heart Association's Council for High Blood Pressure Research, Washington, DC, 2000
	94	Bonafede, et al., <i>Journal of American Chemical Society</i> , 117: 30, 1995
	95	Uusimaa, et al., <i>International Journal of Cardiology</i> , 69: 5-14, 1999
	96	Stanton, B., et al., <i>Journal of Clinical Investigation</i> , 75: 1317-1326, 1985

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

FORM PTO-1449

U.S. DEPARTMENT OF  
COMMERCE, PATENT AND TRADEMARK OFFICEATTY. DOCKET  
NO.: S03417/3APPLICATION NO.:  
10/682,527INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

INVENTOR: Fedde, et al.

Filed: 10/9/03

Group:

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner Initial		
	97	Hou, J., et al., <i>Journal of Clinical Investigation</i> , 96: 2469-2477, 1995
	98	Rocha, R., et al., <i>Hypertension</i> , 33: 232-237, 1999
	99	Young, M., et al., <i>American Journal of Physiology</i> , 269: E657-E662, 1995
	100	Okamoto, K., et al., <i>Circulation Research</i> , 34&35 (Suppl I): I143-I153
	101	Stier, CT, et al., <i>Hypertension</i> , 13: 115-121, 1989
	102	Stier, CT, et al., <i>Journal of Pharmacology and Exp. Therapeutics</i> , 260: 1410-1415, 1992
	103	Sokolo, M., et al., <i>American Heart Journal</i> , 37: 161, 1949
	104	Neaton, JD, et al., <i>JAMA</i> , 270 6, 713-724, August 11, 1993

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609.  
Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(Form PTO-1449)